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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,602	02/08/2002	Michael Toft Overgaard	07039-145001	7259

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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1652	8

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,602	OVERGAARD ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-36 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 8, 9, 11, and 12, in part, and 3 drawn to a method for screening for a growth-promoting state by detecting PAPP-A by measuring protease activity.

Group II, claim(s) 1, 2, 8, 9, 11, and 12, in part, and 4, 6, 7, and 36, drawn to a method for screening for a growth-promoting state by detecting PAPP-A by measuring PAPP-A protein.

Group III, claim(s) 1, 2, 8, 9, and 12, in part, and 5, drawn to a method for screening for a growth-promoting state by detecting PAPP-A by measuring PAPP-A mRNA.

Group IV, claim(s) 1, 2, 8, 9, 11, and 12, in part, and 10, drawn to a method for screening for a growth-promoting state by detecting PAPP-A in a complex.

Group V, claim(s) 13, drawn to a monoclonal antibody for PAPP-A.

Group VI, claim(s) 14, drawn to an agent that modulates PAPP-A protease activity.

Group VII, claim(s) 15-17, drawn to a method for identifying an agent that inhibits the protease activity of PAPP-A.

Group VIII, claim(s) 18-22, drawn to a method for identifying an agent that enhances the protease activity of PAPP-A.

Group IX, claim(s) 23, 26, 27, and 32, in part, and 24 drawn to a medical device comprising an agent that enhances PAPP-A protease activity.

Group X, claim(s) 23, 26, 27, and 32, in part, and 25, 28, 29, 30, and 31, drawn to a medical device comprising an agent that inhibits PAPP-A protease activity.

Group XI, claim(s) 33, drawn to a method for making an antibody to PAPP-A.

Group XII, claim(s) 34 and 35, drawn to drawn to a method for screening for a growth-inhibiting state by detecting PAPP-A.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-XII appears to be that they all relate to PAPP-A. However, Bischof et al, 1982 (in IDS) teach a method for detecting PAPP-A levels in patients with trophoblastic tumors. Therefore, Groups I-XII share no special technical feature as defined by PCT Rule 13.2, as the technical feature linking said Groups does not define a contribution over the prior art. Furthermore, the products of Groups V, VI, IX, and X do not share a special common structural or functional feature while, the methods of Groups I-IV, VII, VIII, XI, and XII do not use the same reagents and/or produce the same results. In addition, the methods of Groups I-IV, VII, VIII, XI, and XII not do comprise all of the methods for making or using the products of Groups V, VI, IX, and X. Accordingly, Groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I:

A. Restenosis;

B. Atherosclerosis;

C. Ovulation;

D. Would healing;

E. Fibrosis; or

F. Cancer.

For Group I:

G. Blood;

H. Urine;

I. Pleural fluid;

J. Oral washings;

K. Tissue biopsies; or

L. Follicular fluid.

For Group VI:

M. IGFBP-4

N. Insulin-like growth factor I; or

O. Insulin-like growth factor II.

For Group VIII:

P. A fragment of IGF; or

Q. IGFBP-4.

For Group X:

R. An antibody;

S. A metalloprotease inhibitor;

T. 1, 10-phenanthroline; or

U. proMBP.

For Group XII:

V. Osteoporosis; or

W. Cancer.

Applicant is required, in reply to this action, to also elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 2, 8, 9, 11, and 12, in part, and 3 encompass species A-F and G-L (Group I);

Claims 15-17 encompass species M-O (Group VII);

Claims 18-21 encompass species P-Q (Group VIII);

Claims 23, 26, 27, and 32, in part, and 25, 28, 29, 30, and 31 encompass species R-U; and

Claims 34 and 35 encompass species V-W.

The following claim(s) are generic: 1, 3, 4, 6, 7, 10-12, 14, 15, 18, 20, 23-27, 32-34, and 36.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As described above, Groups I-XII share no special technical feature as defined by PCT Rule 13.2, as the technical feature linking said Groups does not define a contribution over the prior art, as taught by Bischof et al, 1982. Furthermore, the species of each group of the diseases for A-F, the bodily fluids of G-L, the factors of M-O, the factors of P-Q, the inhibitors of R-U, and the diseases of V-W do not share a special common structural or functional feature.

Thus, if Applicants elect Group I, an election of one of A-F and one of G-L must be

made. If Applicants elect Group VI, an election of one of M-O must be made. If Applicants elect Group VIII, an election of one of P-Q must be made. If Applicants elect Group X, an election of one of R-U must be made. If Applicants elect Group XII, an election of one of V-W must be made.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.